

HAPPENINGS at the SAB

...ensuring a solid technical basis for environmental protection

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"SOCIAL SCIENCES UPDATE"

EDITORIAL

In July, 1999 the SAB Executive Committee (EC) committed the Board to doing more in the area of non-economic social sciences. The inclusion of Dr. Roger Kasperson, a *bona fide* non-economic social scientist to the EC, has added an important source of expertise, knowledge, new ideas, and energy that has allowed additional progress in this area.

In addition, under the direction of Dr. Angela Nugent of the SAB Staff, the Board initiated an SAB Social Sciences Seminar Series (4S). Dr. Nugent has worked with Board members, National Academy of Sciences Staff, Agency personnel, and professional groups to find speakers

who have used successfully some particular aspect(s) of the social sciences to address environmental protection problems.

Since we started the series, the Agency has responded positively, engaging staff and senior managers in the Agency in such a way that they see the 4S as an important contribution to work at Headquarters and in the Regions. This interest is reflected back in pointed feedback that stimulates us to continue and improve the series.

At each session over the past year, a senior social scientist from the academic world has discussed how a social science approach has affected--or could affect--environmental decision-making. A senior Agency manager has responded to the presentation, opening up a discussion between the speaker and the audience. The results of that discussion, which is available "live" via teleconference to Agency personnel outside of Washington, are summarized and both distributed by email and published in *Happenings at the SAB*, our monthly newsletter.

The sessions generally have involved 35-55 participants from across the Agency, with strong representation from the Office of Research and Development, Program Offices and the Regions.

The Table below shows the speakers, topics, and respondents:

In this issue..

Editorial	1
Tentative Calendar for October & November ...	3
Continuation of the SAB Lecture Series	5
Committee Activities in September	8
Status of SAB Reports in Progress	9
Abstracts of New Reports	9
Computer News.....	15
Board Bio	15
Members/Consultants/Staff News	16
Bon Mot	17

**SAB Social Sciences Seminar Series (4S)
Speakers in FY00**

Speaker	Topic	Agency Commenter
Dr. Gary Machlis, University of Idaho	"7% Solution"	Dr. Peter Preuss, Office of Research and Development
Dr. Eugene Rosa, Washington State University	"Programming Your VCR and Other Technology Choices"	Ms. Wendy Cleland- Hamnett, Office of Environmental Information
Dr. Baruch Fischhoff, Carnegie-Mellon University	"Scientific Standards for Public Involvement in Environmental Decisions"	Mr. David Davis, Office of Water
Dr. Everett Rogers, University of New Mexico	"The Diffusion of Environmental Innovations"	Mr. Robert Brenner, Office of Air and Radiation

In response to a questionnaire recently sent to Agency attendees at the 4S, we have a number of comments that indicate that the activity is, indeed, helping the SAB carry out its self-described mission: "To make a positive difference in the production and use of science at EPA." Among the comments were the following:

An Office Director in a Regional Office: "...lecture series such as the one SAB sponsors are helpful because they educate EPA managers and staff on areas where social science research and policy analysis can help."

A social scientist in a different Regional Office: "[The series showed how] social scientists are working in problem-solving capacities". The person was encouraged by the observed "openness to these approaches" among participants, including managers, at the meeting.

A senior advisor in an HQ Program Office: "I value this lecture series greatly as [this office] grapples with these questions all the time and

the lectures enable me to spread the latest thinking into our program office staff."

A staff person in ORD: "(I) found the copies of slides and notes very useful in our work and development of guidance information for the Science Policy Council....I will say, that the discussions and presentations were very helpful in breaking some the stereotypes typically attributed to social sciences."

Respondents indicated an appreciation for the diversity of topics covered. These folks also suggested specific steps for improvement -- everything from better audio-visual tools for participants in remote locations to taking the series "on the road"-- as well as specific topics and speakers.

We plan to address these suggestions as much as we can in the second year of the 4S, the first lecture of which took place on Friday, September 22, 2000, and is summarized elsewhere in this issue of *Happenings*. We are coordinating a schedule for the 4S for FY01 with the goals of including presentations/discussions on the following topics:

Human Vulnerability to Global Environmental Change
(Dr. Roger Kasperson, Stockholm Environment Institute)

Applications of Behavioral Decision Theory
(Dr. Robin Gregory, University of British Columbia)

Risk Communication (Dr. Caron Chess, Rutgers University)

Innovative European Programs of Stakeholder Participation. (Dr. Ortwin Renn, Center of Technology Assessment, Baden-Wuerttemberg)

We look forward to informing you about these events as they occur and would welcome your ideas and reactions to the lecture series.

Donald G. Barnes, Ph.D.
SAB Staff Director

TENTATIVE SAB MEETING CALENDAR FOR OCTOBER AND NOVEMBER

Several of the Federal Advisory Committee Act (FACA) meetings noted below have been announced in the Federal Register (FR), together with additional background information. Readers can automatically receive e-mailed copies of FR Notices by subscribing to the SAB Listserver; see Section Updates below.

If a series of meetings is anticipated, the number of the meeting in the series is indicated in parentheses; e.g., "(#2)".

OCTOBER



12-13	Committee:	Clean Air Scientific Advisory Committee (CASAC)
	Location:	Holiday Inn, Alexandria, VA
	Meeting:	Diesel Health Assessment (#2)
	Chair:	<i>Dr. Joe Mauderly, Lovelace Respiratory Research Institute</i>
	DFO:	<i>Mr. A. Robert Flaak</i>
	Email:	flaak.robert@epa.gov
27	Committee:	Research Strategies Advisory Committee (RSAC)
	Location:	Ariel Rios North, Room 6013
	Meeting:	ORD's Draft Strategic Plan, Teleconference
	Chair:	<i>Dr. W. Randall Seeker, GE Energy and Environmental Research Corporation</i>
	DFO:	<i>Dr. John R. Fowle III</i>
	Email:	fowle.jack@epa.gov

NOVEMBER

1-2	Committee:	Executive Committee (EC)
	Location:	Ariel Rios Building, Room 6013
	Meeting:	Review Meeting and Science and Stakeholder Involvement
	Chair:	TBA
	DFOs:	Dr. Donald G. Barnes Dr. Angela Nugent
	Email:	barnes.don@epa.gov nugent.angela@epa.gov
1-2	Committee:	Executive Committee (EC) Subcommittee
	Location:	Ramada Plaza Hotel, Alexandria, VA
	Meeting:	Dioxin
	Chair:	Dr. Morton Lippmann, New York University
	DFO:	Mr. Samuel Rondberg
	Email:	SamuelR717@aol.com

[To View a Tentative 6 Month Calendar Click Here](#)

OR

GO TO THE SAB WEBSITE www.epa.gov/sab/mtgcal.htm

GLOSSARY OF ACRONYMS

CASAC	Clean Air Scientific Advisory Committee
COUNCIL	(Council on Clean Air Compliance Analysis)
AQMS	Air Quality Modeling Subcommittee
HEES	Health and Ecological Effects Subcommittee
DC	Washington, DC
DFO	Designated Federal Officer (SAB Staff lead)
DWC	Drinking Water Committee
EC	Executive Committee
EEAC	Environmental Economics Advisory Committee
EEC	Environmental Engineering Committee
EHC	Environmental Health Committee
EPEC	Ecological Processes and Effects Committee
IHEC	Integrated Human Exposure Committee
IRP	Integrated Risk Project
RAC	Radiation Advisory Committee
RROS	Risk Reduction Options Subcommittee
RSAC	Research Strategies Advisory Committee
RTP	Research Triangle Park, NC
SAP	Scientific Advisory Panel (FIFRA) (Not SAB affiliated)
TBA	To Be Announced
TBD	To Be Determined

CONTINUATION OF THE SAB LECTURE SERIES

"Science and the Human Side of Environmental Protection"

On Friday, September 22, 2000, the SAB began the second year of its lecture series, "Science and the Human Side of Environmental Protection." Dr. Larry Susskind, Ford Professor of Urban and Environmental Planning and Head, Environmental Policy Group at the Massachusetts Institute of Technology (MIT) and Director, MIT-Harvard Public Disputes Program, spoke on the topic of his forthcoming book to be published by *Island Press*, currently in draft under the title, "Who Says So? The Uses and Organization of Environmental Policy Studies." Twenty-five people from eight Headquarters Offices and five regions participated in the session.

Dr. Susskind started his presentation by describing how his experiences at the not-for-profit Consensus Building Institute mediating multi-party and multi-issue disputes at the local, regional, national and international levels (see <http://www.cbi-web.org/> for more information) had interested him in developing protocols for science-intensive policy disputes. He was particularly curious about disputes marked by a "clash of interests" and by a "need to be grounded in deep understandings of systems natural and social...where scientific and technical analysis needed to be brought into the conversation."

His research was sparked by the observation that opposing interests generally discredited research and information developed to help address a problem when they lacked capacity to create or influence that research or information. He undertook his research project to identify characteristics of policy studies that had success in influencing policy makers. He led a team that conducted case studies of six policy studies at the federal level that were identified as especially important by leaders in policy circles in Washington. His study analyzes the origins, organization, implementation, and utilization of the following policy studies:

1. Regulating Pesticides in Food: The Delany Paradox by the Board on Agriculture of the National Research Council of the National Academy of Sciences
2. Costs and Benefits of Reducing Lead in Gasoline by the US EPA's Office of Policy Analysis
3. Complex Cleanup: The Environmental Legacy of Nuclear Weapons Production by the Office of Technology Assessment
4. Reducing Risk: Setting Priorities and Strategies for Environmental Protection by the Science Advisory Board of the EPA
5. New Farm and Forest Products: Responses to the Challenges and Opportunities Facing American Agriculture by the Task force on New Farm and Forest Products

6. Alternatives for Management of Late-Successional Forests of the Pacific Northwest by the Scientific Panel on Late Forest Ecosystems.

Dr. Susskind noted that these successful studies did not follow the conventional approach taken by most policy analyses. They were remarkable instead for the following features: (1) they defined the policy problem in a helpful way to stakeholders; (2) they described a full range of policy responses, not just the sponsor's understanding of current authorities; (3) they helped overcome Agency resistance to change; (4) they provided important opportunities to engage stakeholders; (5) they provided information that enhanced the legitimacy of a particular action but did not prescribe the action; and (6) they addressed resource priorities. He concluded that the studies did not isolate analysts from policy makers and stakeholders; instead analysts interacted with policy makers and decision makers throughout the process of development.

Dr. Susskind focused most of his presentation on the key phase in designing policy studies when stakeholders and decision makers initially engage the science and analysis. He recommended a course of action for sponsoring Agencies to pursue. He suggested that sponsoring Agencies engage professional "neutrals" to identify "categories" of stakeholders with interests in the policy issue and work with groups within those "categories" to identify participants. He described a process where these "neutrals" would work with stakeholders to develop a map of the conflict which would plot categories of stakeholders and their interests. The "neutral" would gain the sponsor's understanding of this "map" and then develop a process for engaging the issues and involving the stakeholders. He acknowledged that this approach expands on EPA's current use of "facilitators and mediators" and makes use of EPA's existing roster of "neutrals" available on the web.

Dr. Albert McGartland, Director of the National Center for Environmental Economics, had been previously invited to open the discussion with observations and questions. He noted that his first-

hand knowledge of two of the cases gave him an appreciation of the accuracy and careful documentation of the case studies. Although Dr. Susskind had joked that the "keys" to effective policy studies might seem self-evident, Dr. McGartland compared them to the "7 Habits of Highly Effective People," behaviors often overlooked or forgotten.

In terms of policy recommendations, he noted that the Agency had recently invested in building its internal capacity for policy analysis by authorizing hiring of economists in his office. He noted that there may be justification for a broader investment in other kinds of internal Agency policy capacity and that this topic may be an issue for the Agency's Science Policy Council and Regulatory Policy Council. He suggested that Dr. Susskind might consider how specific kinds of "drivers" for policy analysis (such as the legislative and congressional drivers requiring economics analysis) influence the kinds of policy analyses that do and do not get done. He also noted that the "reality base" supporting policy work may have an impact on how effective analyses are in influencing decisions. He observed that the Administrator preferred to cite cases avoided by a given environmental option, rather than refer to levels above or below a safe range as suggested by Reference Doses (RfDs) for non-cancer health effects. He concluded that Dr. Susskind's presentation framed economic analysis within the context of political economy and underscored the importance of designing policy studies appropriately to address institutional and stakeholder needs.

Dr. Susskind responded that his study includes a chapter on selecting methods for policy analyses. He observed that adopting multiple methods is often very helpful; his document contrasts different approaches and discusses how choices might be made among them.

Questions then came from the general audience. A question from Region 7 concerned how analytical processes can rebound from situations where missing information or missing stakeholders have been identified. Dr. Susskind responded that ongoing interactions with stakeholders would allow for a "neutral's" reconvening a stakeholder group to advise on how to factor in new information. Similarly, where there is a contention that a

stakeholder has been omitted from the process, the "mediator" would ask the individual to differentiate their concerns from the categories already identified on the "map" initially identifying stakeholders, and to make their case that their interest is sufficiently distinct from groups currently engaged to the general stakeholder group. In response to another question from the region about the length of time involved in conducting high-quality policy studies, Dr. Susskind responded that it is important to be explicit at the start about the time-frame involved in a process and to build in steps for organizational and public learning about the results of the study into the process.

Then followed a discussion of the importance of having a customer truly interested in the results of a study and poised to act on the results.

The next topic addressed the relationship between the analytic aspects of policy work and the deliberative process - should they be distinct or interwoven. Dr. Susskind advocated that conversations need to happen throughout the process. Problem identification requires stakeholders and the choice of analytical approaches depend on the risk management options. He suggested that "radically wrong results" were more likely to happen if stakeholders were not in the room, than if they were there.

A headquarters participant then raised the issue of stakeholder identification at the federal level. EPA wrestles with different "mental models" of what this term may mean. One model includes all interested and affected parties, basically everyone, since everyone has an interest in the environment. Another model is limited to only the Congress, Office of Management and Budget and the Agency. Finally, the third model limits itself to lobbyists or Trade Associations. Dr. Susskind responded that this question arises because since the 1960's American society has adopted many different kinds of consultative processes, but hasn't spelled out how these processes are to work - either singly or together. He suggested that three different models were in play: (1) a "public hearing model" where "everyone can have a say;" (2) the official,

representative-democratic, electoral model, with acknowledged rules and accountability; and (3) the consultative model, which currently involves *ad hoc* convening of legitimate stakeholders. He suggested that his current study suggests some protocols for providing structure for this third model. A question then followed about how this third model could engage "diffuse" interests like housewives and consumers, who typically do not organize themselves well. Dr. Susskind suggested that mechanisms were available to address their needs. Neutrals could identify existing organizations that met certain criteria for representing these "diffuse" groups; they could cause a new group to be created to represent them; or they could adopt the device of a "stand-in" to act as a guardian of the group's interest

Conversation then turned to the usefulness of the Federal Advisory Committee Act (FACA) as a tool for generating the kinds of effective advice described in Dr. Susskind's manuscript. Dr. Susskind suggested that it is possible, but awkward, to implement the kinds of processes he recommends within the FACA framework. He suggested that, given a choice, he would prefer a substitute for FACA, where Agencies would develop explicit guidance that would implement the processes he described in his book. He suggested that policy studies would be more effective if they were generated by committees that were driven by stakeholders' interests, rather than by committee members' credentials.

Final points in the discussion reiterated the importance of impartial peer review to effective policy studies and the importance of sponsoring Agencies remaining engaged as stakeholders throughout the process of developing policy studies.

The SAB plans to host lectures on the social sciences on a periodic basis to highlight how the social sciences can help solve actual environmental problems. If you have suggestions for future speakers or topics, please contact Angela Nugent (202-564-4562 or nugent.angela@epa.gov).

COMMITTEE ACTIVITIES IN SEPTEMBER



On September 20, the Environmental Engineering Committee (EEC) held a teleconference in Washington, DC. The Committee discussed past accomplishments, activities underway, and preliminary plans for FY 2001. The Committee

approved the draft Commentary on Measures of Environmental Technology Performance with minor edits, agreed on a process to approve the draft commentary on Diffusion and the report of the Natural Attenuation Subcommittee.

The EEC also heard very short briefings on requests for FY 2001 reviews from the Office of Solid Waste and the Office of Research and Development. The committee will reconvene in December.

On September 20-22, the Ecological Processes and Effects Committee (EPEC) met in Washington, DC to continue its strategic project to describe and apply a framework for reporting on ecological conditions. The Committee is drafting a white paper describing essential ecological attributes that should be included in reporting schemes, including those devised to report on Government Performance and Results Act (GPRA) goals. At the meeting, the Committee was briefed on a variety of EPA environmental reporting efforts, as well as the U.S. Forest Service's Forest Health Monitoring program. The Committee's final report will include case examples to illustrate potential applications of their reporting framework for EPA programs and projects.

On September 22, the Executive Committee (EC) met in Washington, DC to complete the following actions and issue the following instructions.

ACTION 1:

The Executive Committee approved the Environmental Health Committee's "Review of the

Agency's Draft Report to the Congress: 'Characterization of Data Uncertainty and Variability in IRI S Assessments, Pre-Pilot vs. Pilot/post-Pilot'" subject to edits referenced in the meeting. Dr. Greer abstained.

ACTION 2:

The Executive Committee approved the Drinking Water Committee's "Report on Certain Elements of the Proposed Arsenic Drinking Water Regulation", subject to final approval by the two Discussants (Drs. Lippmann and Seeker) and Dr. Greer, acting as authorized vettors on behalf of the EC.

ACTION 3:

The Executive Committee approved the Integrated Human Exposure Committee's "Review of the Draft Strategy for the Analysis of NHEXAS Data," subject to final edits referenced in the meeting.

ACTION 4:

The Executive Committee approved the Drinking Water Committee's "Advisory on EPA's Draft Contaminant Candidate List (CCL) Research Plan", subject to final edits discussed at the meeting.

INSTRUCTIONS

INSTRUCTION 1:

Dr. Lippmann asked Dr. Greer to transmit the comments of Dr. Allen Smith on the DWC report to Dr. Barnes for distribution to the entire EC.

INSTRUCTION 2:

EC members should email to Dr. Barnes within two weeks their suggestions of actual SAB experience that both demonstrate the problem (i.e., formulation of a charge resulting in a request for information or an assignment of a task to the Agency or the SAB that could not plausibly be accomplished on the basis of existing information) and positive examples (i.e., instances of especially well-formulated charges to the Agency or the SAB, or cases in which advance dialogue avoided what might have otherwise been an implausible charge.

INSTRUCTION 3:

Dr. Barnes will have Dr. Nugent set up a conference call with Drs. Morgan, Bull, and Young to discuss the up-coming workshop session on science and stakeholders.

INSTRUCTION 4:

Dr. Fowle will work with Drs. Schnoor and Seeker on the feasibility and advisability of having a joint Consultation with SAB and BOSC on ORD's new strategic plan.

INSTRUCTION 5:

The EC instructed SAB Staff to distribute the SAB policy on the respective roles of Members and Consultants to all SAB Members and Consultants by Monday, Sept. 25.

EPEC

- 2) Review of Eco-Risk Report Card

IRP/EEC

- 3) IRP Risk Reduction Report

c PROJECTS THAT DO NOT REQUIRE EC APPROVAL

There are no reports at this time.

d PROJECTS THAT HAVE RECEIVED EC APPROVAL AND AWAIT COMPLETION

DWC

- 1) Review of Arsenic

SAB REPORTS IN PROGRESS



a PROJECTS DUE FOR REVIEW AT THE NOVEMBER 1-2 EC MEETING

EEC

- 1) Commentary on Diffusion
- 2) Commentary on the Measures of Environmental Technology Performance

RAC

- 3) Advisory on GENII Version 2.0
- 4) Advisory on TENORM

b PROJECTS DUE FOR LATER EC MEETINGS

EEC

- 1) Review of Natural Attenuation

ABSTRACT OF NEW REPORTS



a Review of the Draft Cancer Risk Assessment Guidelines' Application to Children EPA-SAB-EC-00-016

The Cancer Risk Assessment Guidelines Review Subcommittee (CRAGRS) of the US EPA Science Advisory Board (SAB) met on July 27 and 28, 1999, in Arlington Virginia to provide advice and comment to the EPA on applying EPA's proposed revised Cancer Risk Assessment Guidelines (GLs) to children. The Agency sought advice on the adequacy of the GLs when dealing with assessing risks to children.

The majority of the Subcommittee membership urges EPA to issue the Guidelines promptly (with attention

to the suggestions in this report) and then undertake a program of research and risk assessment improvement that will enable it to address the childhood susceptibility issue more completely in future revisions of the Guidelines.

The Subcommittee examined the use of a linear default approach and most Members agreed that the linear default approach was sufficiently conservative; others believed that the current procedure could mispredict risk.

The Subcommittee believes that the Mode of Action (MOA) Framework for analysis of data proposed by the Agency, should be relevant for most subpopulations of concern, but was unable to reach a consensus on the default use of a 10-fold adjustment factor. The Members did agree the population response threshold for children could be lower than for adults for some carcinogens acting through a non-linear mode of action. There was consensus that if EPA were to use such a factor, it should be dependent on the state of the database and not be based on a single default number. The Subcommittee agreed that EPA should evaluate the acceptability of an margin of exposure (MOE) on a case-by-case basis, supported by a narrative.

Some Members supported EPA's default assumption that the mode of action should not be considered operative in children and that a linear dose-response relationship should be used unless agent-specific data are available; others found the default assumption and policy inconsistent with the GL's general conclusion that the mechanisms of carcinogenesis are similar between children and adults.

The Subcommittee noted that EPA's default approach for converting an equivalent dose for adults to an equivalent dose for children is unclear and needs better definition, but agreed with the approaches to adjusting slope factors for lifetime and partial lifetime exposure scenarios to reflect data on early-life sensitivity.

The Subcommittee also evaluated the responsiveness of the draft guidelines to the questions posed by the EPA Children's Health Protection Advisory Committee in its May 12, 1999 letter to Administrator Browner. Although the Committee judged some of the responses to be adequate, others were found to be rather perfunctory and incomplete.

**b Consideration of issues relating to EPA's use of data derived from the testing of human subjects
EPA-SAB-EC-00-017**

The Joint Science Advisory Board/Scientific Advisory Panel (SAB/SAP) Data from Testing on Human Subjects Subcommittee (DTHSS) first met on December 10-11, 1998, in Arlington VA, to discuss the use of data generated by testing human subjects. The Charge addressed a wide range of issues on the ethics and efficacy of such testing. After generating a series of drafts, the Subcommittee met a second time in Arlington, VA on November 30, 1999 to discuss issues on which consensus had not been reached.

The most significant findings are best expressed outside the specific Charge issues. The findings on which the Subcommittee was unanimous are:

- a) Any policy should reflect the highest standards of respect for human subjects.
- b) The threshold of justification for exposing human subjects to toxic substances should be very high.
- c) Bad science is always unethical.
- d) The only justification for the use of human subjects in pesticide testing is to better safeguard public health.
- e) Testing policy must reflect a special concern for vulnerable populations (fetuses, children, adolescents, pregnant women, the elderly, and those with fragile health).

<p>f) Unintended exposures provide valuable opportunities for research.</p>	<p>available from field exposure studies.</p>
<p>g) EPA must consider the distribution of risks and of benefits, and to ensure that risks are not imposed on one population to provide benefits for another.</p>	<p>3) Human studies could be appropriate when there are significant data gaps.</p>
<p>All but two of the Subcommittee Members agreed on circumstances when dosing humans with toxic agents could be acceptable. The following guidelines were cited by these Members:</p>	<p>4) Human studies could be appropriate for pesticides which are not yet on the market.</p>
<p>a) All research involving humans should require prior review by an Institutional Review Board (IRB).</p>	<p>5) EPA should organize a workshop to deal with the statistical considerations in human study design.</p>
<p>b) The structure/function/activities of IRBs should be under active and aggressive scrutiny.</p>	<p>c Review of NHEXAS EPA-SAB-IHEC-00-018</p>
<p>c) The intentional administration of pesticides to human subjects testing is acceptable, subject to limitations ranging from "rigorous" to "severe."</p>	<p>EPA's Office of Research and Development has carried out a series of pilot studies known collectively as the National Human Exposure Assessment Survey (NHEXAS). The NHEXAS studies tested protocols for acquiring population distributions of exposure measurements and developed exposure databases for use in exposure models, exposure assessment, and risk assessment. The actual data collection was accomplished by three consortia, employing the same basic set of questionnaires, but using some different methodologies.</p>
<p>d) Developing humans (the fetus, infants, young children, or adolescents) should never be exposed to neurotoxic chemicals.</p>	<p>In 1998, the SAB's Integrated Human Exposure Committee (IHEC) recommended that EPA develop a strategic plan for the analysis of the NHEXAS Pilot Study Data. EPA developed such a plan and the IHEC met on July 10-11, 2000, in Research Triangle Park, North Carolina to review it by discussing the Strategy's completeness/inclusiveness; its strategic presentation/prioritization of projects; its usefulness for resource allocation; and its utility for providing guidance for developing useful analysis tasks.</p>
<p>e) The EPA should extend the protections of 40 CFR Part 26 to all human research activities submitted to the Agency.</p>	<p>Looking at the effort globally, the Committee concurred that the NHEXAS strategic plan represented a remarkable effort and that its authors should be</p>
<p>f) Research done unethically should not be rejected automatically.</p>	
<p>g) Situations in which such testing would or would not be appropriate include:</p>	
<p>1) No such testing should be conducted when adequate human data are already available.</p>	
<p>2) Testing would not be appropriate when data of equal quality is</p>	

congratulated. The Committee suggested that EPA review long-term support needs to ensure that the necessary resources will be available. Addressing the specific issues, the Committee felt that EPA set priorities well, but was concerned that too much was being proposed. Also, some effort should be made to include some geographic information which will permit analysis of the data in geographic information systems.

The Committee agreed the data analysis strategy was well done and well presented, but also recommended that EPA: promote greater multi-disciplinary integration, including linking exposure data with health risk assessments; emphasize work predicting exposure; set priorities across topic areas, and assess whether they address EPA management policy priorities; subdivide large projects; integrate the data collected by the three consortia into a single comparable database; and review previously published work to avoid redundancy.

The Committee felt that the draft Strategy's prioritization of projects was well executed. Recommendations advised EPA to: provide estimates of time and cost for projects; prioritize highly ranked projects from different areas; consider the timing of the projects vs. the schedule for attaining various policy goal; "market" the data to other EPA offices and other agencies; and develop a five to seven year operational plan.

Addressing the issue of how well the strategy provided guidance to scientists for developing the most "useful" analysis tasks, the Committee first noted that the answer to this question is not straightforward, since the definition of "useful" can be interpreted in different ways by the many diverse communities of scientists who could be potential users of the data. With that caveat, the Committee agreed that the draft Strategy provides adequate guidance to scientists both inside and outside EPA who are already familiar with the exposure assessment field, the NHEXAS effort, and the needs of the Agency. With respect to usefulness, the Committee offered the caveat that the strategy could benefit from additional guidance on applying the

four basic criteria to potential projects that cut across the different topic areas presented.

The Committee also recommended that EPA: expand the universe of researchers who could respond to NHEXAS-related proposals; ensure quality as much as possible before the data is posted; and consider how to distribute the NHEXAS information to the public.

d Review of the Draft Report to the Congress
"Characterization of Data Uncertainty and
Variability in IRIS Assessments, Pre-Pilot vs.
Pilot/Post-Pilot"
EPA-SAB-EHC-LTR-00-007

The Environmental Health Committee (EHC) of the US EPA Science Advisory Board (SAB) met on August 30, 2000, in Washington, DC to fulfill a Congressional directive to review (and to provide advice and comment on) EPA's mandated study of the Integrated Risk Information System (IRIS). The EPA study plan reflected the advice received from an earlier Consultation with the SAB Executive Committee.

The Committee agreed that:

- a) the Agency did a good job implementing the study plan, but commented on a major point: variability, as used by the study, covered both uncertainty and what is traditionally covered by variability, rather than separating them. This may have resulted from an interpretation of the Congressional language calling for an evaluation of the IRIS documentation of "the range of uncertainty and variability of the data." Some Members were concerned that the study did not fully address what may have been the underlying concern of Congress -- the extent to which the IRIS documentation provides a reasonable description of the intrinsic uncertainty in a given human health risk assessment, and an estimate of the extent of variability of human risk.

- b) the study reviewers had followed their mandate and reached overall conclusions that were reasonable.
- c) the description of uncertainty could be significantly improved for most pre-pilot chemicals, and such descriptions have improved significantly since the initiation of the pilot program. The Committee also agreed with general recommendations for improvement of characterizations of uncertainty and variability.

The draft report does not come to any overall conclusion about the adequacy of uncertainty and variability information in the IRIS documentation, and provided several suggestions to improve IRIS performance on these factors:

- a) EPA should include more information on uncertainty and variability in every chemical summary that would have been rated less than extensive by the reviewers. This could be accomplished by developing a detailed protocol for completing an adequate documentation of uncertainty and variability.
- b) EPA should also develop a strategy for *reducing* uncertainties where these severely compromise the utility of IRIS evaluations.
- c) EPA should investigate the feasibility of providing more information that can help answer the underlying question about the uncertainties and variabilities in human health risk assessments based on the IRIS toxicity numbers.
- d) EPA might characterize the toxicity of chemicals through distributional analyses of toxicity, as well as of exposure, in human health risk assessments.

The Committee also noted that:

- a) The request from the Congress indicates that it is driven by "...concern about the accuracy of information in the IRIS data base..." For IRIS to be of greatest value to the Agency, the database must be current, and there should be a mechanism for the IRIS data to be subjected to external scientific and independent peer review. The IRIS should be capable of timely and continuous revision. The mandate for adding new agents, plus the need to revise the documentation on the current agents, exceeds the resources allocated by the EPA to this task. The Agency should consider collaborative efforts with outside institutions, such as the National Academy of Sciences to expedite the generation of IRIS files.
- b) The IRIS staff should make the best possible use of the IARC, the Agency for Toxic Substances and Disease Registry, and other documents so as to avoid duplication of effort and make their own reviews easier to conduct. They should also seek to cross-reference these other reviews. In this way, EPA could focus on improving the quality of input data, eliminating redundant compilations of the same data and developing single "gold standard" evaluations for all important compounds. Near term efforts should emphasize the development of IRIS documents on chemicals with significant environmental exposures that are not currently on IRIS, or for which the IRIS is believed to be inaccurate, out-of-date, or non-informative.
- c) EPA should relatively quickly decide how it will deal with the concern that children might be at greater risk from certain environmental chemicals than adults.

e **Commentary and Recommendations on Overcoming Barriers to Waste Utilization**
EPA-SAB-EEC-COM-00-006

The Environmental Engineering Committee of the USEPA's Science Advisory Board prepared a commentary on overcoming barriers to waste utilization.

The growth in industrial activities to support a growing population implies that the volume of wastes from energy production, mining, industrial processing, manufacturing, and municipal operations will continue to increase. Although research and technology development in the waste utilization arena are expanding, tools are needed to advance these technologies and efforts to the implementation phase. Encouragement of the existing Comprehensive Procurement Guidelines, regulatory incentives or changes, a formalized demonstration project program, and a regulatory framework or national guidance are all concrete actions that can be taken to promote waste utilization.

However, the role of economics in this process cannot be overstated. Without economics as the driver for waste utilization, our recommendations will miss the mark. The EEC recognizes the importance of economics in helping the Agency focus attention on wastes that are the most attractive for large-scale recycling. Clarification of roles for all stakeholders is essential if success is to be achieved. By forming partnerships between industry and agency leaders, the proper balance of environmental stewardship and economic viability can be found.

f **An SAB Advisory on EPA's Draft Contaminant Candidate List (CCL) Research Plan**
EPA-SAB-DWC-ADV-00-007

The Drinking Water Committee (DWC) of EPA's Science Advisory Board (SAB) began its review of the Agency's draft Contaminant Candidate List Research Plan on August 8-9, 2000. The draft Research Plan (EPA 2000) addresses five issues:

- a) the Agency's plan for identifying and ranking Contaminant Candidate List 1 research needs,
- b) the analytical methods needed to address contaminant occurrence/exposure/health effects/treatability,
- c) occurrence and exposure associated with the contaminants in source water/finished water/distribution systems,
- d) the existence of significant health risks for the contaminants, and
- e) the effectiveness of treatment technologies for controlling these contaminants.

The Drinking Water Committee commended the Agency for its progress in developing a research plan to addresses the program needs and the research resources available to the EPA. The Committee noted the substantial progress made since it was first briefed on the information needs to support the CCL program during Fiscal Year 1999. When complete, this plan will fill an important need both within EPA and as a communication instrument to interested parties outside the agency.

The nature of the charge questions demonstrates that the Agency has a good grasp of the tasks that the CCL Research Plan must address. During the first review meeting, the Committee recognized both from the Agency's briefing and the discussions on the charge questions that ensued that it did not have sufficient information on the individual contaminants and the process and procedures used by EPA to arrive at their current version of the plan and to completely respond to the charge questions. It also became clear that additional information is available and could be supplied to the Committee. As a consequence, the Committee decided to conduct the review in two stages. The first was the August 2000 meeting, the results of which are now provided to the Agency in this Advisory report. The second will be a meeting scheduled for January 2001 after the Committee receives additional information and a revised version of the draft research plan. The Agency has agreed to provide additional information to the Committee including at least:

- a) the notebook of "Health Effects Data Summaries" (CD format would be helpful);
- b) the AWWARF workshop report - actually delivered to the DWC during the August meeting, and
- c) occurrence data used in developing CCL1.

The Committee suggested that the Agency consider responding to comments made in the August meeting about the clarity and content of the current draft research plan by developing a revised research plan and asked EPA to determine whether there are other documents that could be provided to help the Committee better understand the Agency's development of the CCL research process.

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COMPUTER NEWS



(1) SAB Website is within the EPA Home Page. You are invited to visit the SAB Website at URL:

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- (a) Full-text reports for FY1994-FY2000
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- (c) A rolling two-month calendar of SAB meetings
- (d) The most current issue of HAPPENINGS
- (e) Draft/final agendas of upcoming meetings and draft/final minutes of past meetings.
- (f) And much, much...well, maybe a little bit more!

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BOARD BIO



r. Calvin Chien has been serving on the Environmental

Engineering Committee (EEC) and Environmental Modeling Subcommittee (EMS) with the SAB since 1992. Calvin came to this country in 1968 after finishing his undergraduate engineering degree in Taiwan.

He continued his studies at the State University of New York at Buffalo (SUNY) and received his Ph.D. in 1974. His thesis focused on the area of modeling of hydrologic systems.



Calvin joined the DuPont Company in 1981 after working with an international consulting company and Westinghouse. Currently, he is a Senior Environmental Fellow with DuPont and works in the company's Corporate Remediation Group in Wilmington, Delaware. Since late 1980, Calvin has been responsible for providing technical

site environmental support for DuPont's sites in the Asia Pacific Region, focusing largely on the natural resources and soil and water contamination and remediation. This work has allowed him to develop an extensive network of contacts from academia, industry, and governmental agencies in many countries in this region. Calvin has presented speeches and served as panel leader to the special China Forums, including those sponsored by the U.S. Department of Defense, Harvard University, and the National Environmental Forum in China.

In addition to working in the Asia Pacific Region, Calvin has also served as an Environmental Remediation Technology leader with DuPont since 1991. In this role, he has led his team in the evaluation and development of the containment technology and environmental modeling technology. Calvin is widely recognized for his vision, effort, and leadership in teaming with the U.S. Environmental Protection Agency and the U.S. Department of Energy to make containment a better understood, further improved, and more accepted measure of environmental remediation. In a similar partnership with industry, academia, and governmental agency experts, Calvin organized the recent workshop, with four panels served by 50 invited experts, entitled "Modeling and Management of Emerging Environmental Issues." The workshop tackled modeling issues that have puzzled modelers and sought to identify solutions and research needs.

Besides EPA/SAB, Calvin has been invited by other federal agencies, including USDoe and the National Science Foundation, to serve on a number of technical review/evaluation committees in the past ten years.

Throughout his career, Calvin has received many honors and awards, including the Westinghouse Invention Award and DuPont Major Contribution Award. He also was the first alumni recipient of Asian heritage to receive the highest honor that the SUNY Engineering School offers, the Dean's Engineering Achievement Award.

Calvin's passion for engineering is superseded only by his love for long-distance running. To

encourage others in the sport (and provide levity at work), Calvin challenges his colleagues no greater than 10 years his junior to compete in a one to five mile race. The challenge is legendary, and he has lost only once to a colleague eight years his junior.

Calvin's wife and high school sweetheart, Amy, is a physicist by education and also works for DuPont. They have two daughters, Janet and Angela. Janet graduated from Yale and is now a physician, and Angela has just started at Columbia Law after graduating from Harvard.

MEMBERS/CONSULTANTS/STAFF NEWS



Dr. Mort Lippmann (SAB Interim Chair, NY University) and Phil Hopke (SAB Residual Risk Subcommittee Chair, Clarkson University) testified before the Senate Environment and Public Works Committee as a part of a hearing on comparative risk and residual risk. Both men drew upon their SAB experiences to share their views on the role of science in environmental decision-making at EPA. Their written testimony can be found on the SAB Website (www.epa.gov/sab).

In addition, on October 2, Dr. Hopke briefed Congressional staff on the findings, conclusions, and recommendations stemming from the Subcommittee's review of the Agency's Residual Risk analysis of secondary lead smelters.

BON MOT

Bumps along the road into the hi-tech world



1. "Would anyone else like a BLT?"

A large new motor home was towed into the dealership's garage. The front of the vehicle was in dire need of repair. When asked by the manager what had happened, the driver replied that he had set the cruise control, then gone in the back to make a sandwich.



2. "While you're up, get me some paper, too."

Boss: "Hey, I'm almost out of typing paper. What do I do?"

Secretary: "We'll just use copier machine paper."

Boss: "OK. I'll get it, while you finish up your project."

With that, he took his last remaining blank piece of paper, put it on the photocopier, and proudly made five blank copies.